

## REMARKS

Claims 1-5, 85-201, 260-263 were designated for prosecution in this application, and the remaining non-elected claims 6-84 and 202-259 are being retained in this application, unexamined, pending allowance of a generic or linking claim.

Allowance of claims 5, 131, 133, 138, 139, 260 and 261 is noted with appreciation. Rejected claims 99, 112, 121, 127, 155, 171, 173, 175, 182-184, 191, 194, 195 and 198-200 have been cancelled without estoppel or disclaimer of the subject matter thereof.

Claim 193 has been rejected under 35 U.S.C. § 112, ¶ 2, for depending from a cancelled claim. The dependency of this claim has been corrected to define the invention with sufficient particularity and distinctiveness to be patentable to Applicant.

Claims 1 and 4 have been provisionally rejected under the judicially-created doctrine of obviousness-type double patenting as being unpatentable over claim 5 of co-pending Application No. 10/726,803 in view of Redtenbacher et al '847. This rejection is respectfully traversed with respect to these claims as amended herein.

Specifically, claim 5 of Ser. No. 10/726,803 includes such recitals as “location relative to a femoral artery below the inguinal ligament”, and “the

selected location is covered by a substantially intact portion of the epidermis. . .” as a claim which the Examiner notes is of narrower scope than these pending claims.

Additionally, Redtenbacher et al ‘847 is understood to disclose merely an intraluminal use of an endoscope (e.g., within the esophagus) and is not understood to establish an opening via an endoscope from outside such lumen (that is not a blood vessel, as claimed by Applicant). Nor is there any instruction reasonably derivable from the co-pending claimed subject matter (otherwise than from Applicant’s own specification), or from the cited reference including at the cited passages at column 3 and at columns 6 to 7 for the combination proposed by the Examiner. It is therefore respectfully submitted that claims 1 and 4 as amended are now patentable to Applicant.

Claim 1 has been provisionally rejected under the judicially-created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of co-pending Application Ser. No. 10/824,043 in view of Redtenbacher et al ‘847. This rejection is respectfully traversed with respect to this claim as amended herein.

Claim 1 of the co-pending application includes such recitals as “. . . expose a femoral artery”, and “performing an aortotomy . . . through the lumen of the surgical instrument” as a claim which the Examiner notes is narrower in scope than the present claim. And, the deficient disclosure of Redtenbacher et al ‘847 including the cited passages in columns 3 and columns 6-7, as discussed in the above Remarks, fails to establish even a *prima facie* basis from which a proper

determination of obviousness can be formed. It is therefore respectfully submitted that claim 1 is now patentable to Applicant.

Rejected claim 171 has been cancelled.

Claims 85, 86, 91, 114, 128, 129, 141, 157 and 170 have been rejected under 35 U.S.C. § 102(e) as being anticipated by Kaster '447. This rejection is respectfully traversed with respect to these claims as amended herein.

The independent claims variously recite the method including “attachment end within a passageway of a delivery device; advancing the delivery device toward the anastomosis site from outside the vessel while the blood-conveying conduit and attachment end are located within the passageway of the delivery device”, and “removing the blood-conveying conduit and attachment end from within the passageway of the delivery device after the advancing step”, or “advancing the distal end of the delivery device toward the anastomosis site from outside a vessel including the anastomosis site while the graft and attachment end are located within the passageway of the delivery device”, or “removing the blood flow conduit and attachment end from the interior space after the advancing step”.

In addition, the dependent claims variously recite the method including “the delivery device holds the blood-conveying conduit in a linear configuration”, or “the aorta attachment end is removed from within the passageway of the delivery sheath prior to removal of said another vessel attachment end from the passageway.”

These aspects of the claimed invention are not disclosed or even suggested by Kaster et al '447 which relies upon an annular staple as an attachment device on an end of the conduit (blood vessel 51) all disposed outside interior space of a delivery sheath. Indeed, a blood vessel 51 in this reference is inverted over the distal end of a delivery sheath to cover the distal end and an annular staple positioned there. Clearly, the annular staple and inverted end of a blood vessel form the attachment end (to a vessel 53) disposed outside the delivery mandrel 16 where they are vulnerable to being damaged or to damaging adjacent tissue structures upon insertion toward the anastomosis site. It is therefore respectfully submitted that Kaster et al '447 fails to disclose the specifically-recited aspects of the claimed invention which is therefore not anticipated by, but which instead is patentably distinguishable over Kaster et al '447.

Rejected claims 99, 127, 155, 173, 175, 182-184, 191, 194, 195 and 198-200 have been cancelled without estoppel or disclaimer of the subject matter thereof.

Claims 90, 92, 97, 98, 119, 122, 146, 153, 154, 162, 169 and 186 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Kaster et al '447 in view of Palmaz '665. This rejection is respectfully traversed with respect to these claims as amended herein.

These dependent claims are further limited over the respective preceding claims by various recitations such as "the attachment end of the blood-conveying conduit is located at a first position within the passageway near a distal end of the

delivery device” and “a body of the blood-conveying conduit and attachment end are interposed between the first position and the second position within the passageway”, or “advancing the distal end of the delivery device toward the anastomosis site while the attachment end of the blood-conveying conduit is located within the distal end of the delivery device”, or “the attachment end is removed from within the passageway of the delivery device through a distal end thereof prior to removal of the other end from within the passageway through the distal end”.

In addition, independent Claim 186 specifically recites “advancing the delivery device toward the anastomosis site from outside the vessel while the full length of the graft and attachment end are contained within the delivery device; and removing the graft and attachment end from within the delivery device after the advancing step”.

These aspects of the claimed invention facilitate delivery of the graft to the anastomosis site with the attachment end contained within the delivery device to protect the attachment end and surrounding tissue from damage during positioning of the distal end of the delivery device from outside the vessel.

These aspects of the claimed invention are not disclosed or even suggested by Kaster et al ‘447 or by Palmaz ‘665 considered either alone or in the combination proposed by the Examiner.

In addition to the details discussed in the above Remarks, Kaster et al '447 requires an attachment end to be disposed outside the delivery device and to have the conduit or graft exposed over the distal end in convoluted or inverted configuration during delivery and placement at the anastomosis site. And, Palmaz '665 discloses an intraluminal delivery technique for delivering a stent, with no motivation found in this reference for a combination with Kaster et al '447 that in any way cures the deficient disclosure of this reference regarding the Examiner's analysis of "the conduit end (distinctively not an attachment end as claimed by Applicant) or the entire conduit within the delivery device." Nor can one of these cited references be modified in the proposed combination by the other reference without altering the diverse objectives or purposes of the references either to deliver a stent intraluminally or to perform an end-to-side anastomosis. It is therefore respectfully submitted that these claims as amended are now patentably distinguishable over the cited art.

Claim 263 has been rejected under 35 U.S.C. § 102(e) as being anticipated by Wilk U.S. 5,261,861 (sic: 5,287,861?) This rejection is respectfully traversed with respect to this claim as amended herein.

Specifically, this claim recites "advancing a medical instrument upstream within the circulatory system toward the occluded segment from a location downstream thereof", and "guiding the distal end portion of the medical instrument out of the circulatory system through an opening formed in the circulatory system

downstream of the occluded segment to extend a first portion of the medical instrument outside of the circulatory system with a second portion of the medical instrument located within the circulatory system”.

These aspects of the claimed invention obviate penetrating the vessel occlusion in order to bypass the occlusion. These aspects of the claimed invention are not disclosed or even suggested by Wilk ‘861 that requires insertion of a delivery device downstream through the occlusion from an upstream location in order to deliver a conduit “outside” the vessel, according to the Examiner’s analysis of this reference. Thus, no analysis or proposed modification of this reference can be consistent with or even suggestive of Applicant’s claimed process without also altering the purpose or function of the reference. It is therefore respectfully submitted that claim 263 as amended is not anticipated by but instead is now patentably distinguishable over Wilk ‘861.

Claim 1 has been rejected under 35 U.S.C. § 103(a) as being unpatentable over Kaster et al ‘447 in view of Redtenbacher et al ‘847 or Avant et al ‘039. This rejection is respectfully traversed with respect to this claim as amended herein.

As amended, claim 1 specifically recites “endoscopically creating from outside the blood vessel an opening into the blood vessel at a selected location” and “endoscopically forming from outside the blood vessel an anastomosis between the blood-conveying conduit and the opening created into the blood vessel at the selected location”.

These aspects of the claimed invention obviate limitations of incising tissue from within a vessel or tubular member within the body. These aspects of the claimed invention are not disclosed or even suggested by the references considered either alone or in the combination proposed by the Examiner.

In addition to the deficiencies of disclosure in Kaster et al '447 as discussed in the above Remarks, this reference also fails to disclose, as the Examiner notes, any endoscopic procedures outside of a vessel for both creating an opening in the vessel and creating an anastomosis therewith. And, Redtenbacher et al '847 only discloses intraluminal procedures associated with an endoscope. In the passages cited by the Examiner in column 3, and elsewhere in this reference, it should be noted that the guide journal and other attachments to the endoscope are positioned at the end of the instrument for insertion into the tubular body member (i.e., intraluminally within the esophagus), and not for performing tasks from outside a blood vessel as specifically claimed by Applicant. Similarly, Avant et al '039 discloses procedures performed within a hollow tube-like body using a ligator assembly introduced for example, via the urethra into the prostate, bladder and associated organ (Figs. 2A-2F; col. 2, lines 5-14). There is therefore no disclosure and no hint of suggestion or instruction contained in these references considered either alone or in the combination proposed by the Examiner for performing Applicant's claimed endoscopic procedures from outside a blood vessel. And, any analysis or modification of Redtenbacher et al '847 or of Avant et al '039 that



incorporates extravascular endoscopic procedures (Kaster et al '447 admittedly does not) would constitute an impermissible alteration of the purpose or function of the references involving speculation and hindsight reconstruction of the references using Applicant's own specification. These references are therefore submitted to be deficient of sufficient disclosure to establish even a *prima facie* basis from which a proper determination of obviousness can be formed. It is therefore respectfully submitted that claim 1 is now patentably distinguishable over the cited art.

Allowability of claim 121, subject to the basis for objection, is noted. This dependent claim has been cancelled and rewritten in independent form as new claim 264 to incorporate all the limitations of the base and intervening claims. As written in independent form, this claim is now submitted to be patentable to Applicant.

Allowance of claims 5, 131, 133, 138, 139, 260 and 261 is noted with appreciation.

The Examiner's comments regarding the Applicant's arguments have been considered in amending the claims herein to clearly distinguish Applicant's claimed subject matter from the cited references. Amendments made herein to the claims are merely to define the invention with greater particularity and distinctiveness, and predominantly refer variously to procedures performed outside a vessel, or to the attachment end of a graft or conduit, or to the positioning thereof

within a delivery device. These aspects of the claimed invention are clearly disclosed in the parent application as filed, for example, with reference to Figures 6-8, 9A-11B, 12-16, 190, 26 and 27 and the associated written descriptions.

Co-pending applications which may be considered to contain claims directed to similar subject matter as claimed herein are listed as follows:

Serial No. 09/903,831;

Serial No. 10/726,803;

Serial No. 10/824,043; and,

Serial No. 11/269,929.

Copies of the claims currently pending in these listed applications are believed to be currently available to the Examiner in image format in the IFW System, and are therefore not submitted herewith. However, in the event such claims are not so available, then upon the Examiner's request, Applicant shall provide copies of such claims.

Reconsideration and allowance of all pending claims are solicited. The Examiner is invited to contact the undersigned attorney for the Applicant regarding any remaining issue that may expedite favorable disposition of this Application.

Respectfully submitted,  
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